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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,451	06/05/2006	Francois Ichas	REGIM 3.3-073	8046
530 7590 07/20/2010 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER FRONDA, CHRISTIAN L				
ART UNIT		PAPER NUMBER		
1652				
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07/20/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,451

Applicant(s)

ICHAS ET AL.

Examiner

CHRISTIAN L. FRONDA

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-29 is/are pending in the application.
4a) Of the above claim(s) 8-25 and 27-29 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3, 5-7 and 26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 04 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/1/10
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-3, 5-29 are pending in the instant application. Claims 8-25 and 27-29 have been withdrawn from further consideration as being drawn to a nonelected invention.
2. Claims 1-3, 5-7 and 26 are under consideration in this Office Action.
3. The rejection of claims 1-3, 5-7 and 26 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of the claim amendment and arguments filed 03/01/2010.
4. The rejection of claims 1-3, 5-7 and 26 under 35 U.S.C. 102(b) as being anticipated by Wolter et al. has been withdrawn in view of the claim amendment and arguments filed 03/01/2010.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3, 5-7 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the demonstration of the occurrence of an apoptotic event in a cell comprising detecting the presence of the GFP fused to the N-terminal of Bax comprising the amino acid sequence of SEQ ID NO: 2; does not reasonably provide enablement for other embodiment. The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. MPEP § 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the amended claims encompass any method for the demonstration of the occurrence of any specific molecular event in any cell comprising detecting the presence of any solubilized marker protein or any bound marker protein in the cell wherein the cell is subjected to a permeabilization of the plasma membrane before the detection of the marker protein.

The specification provides guidance, prediction, and working examples for a method for the demonstration of the occurrence of an apoptotic event in a cell comprising detecting the presence of the GFP fused to the N-terminal of Bax comprising the amino acid sequence of SEQ ID NO: 2. However, the specification does not provide guidance, prediction, and/or working examples for making and/or using the invention as claimed. The specification does not provide guidance, prediction, and/or working examples regarding demonstration of any other molecular event other than an apoptotic event. The specification does not provide guidance, prediction, and/or working examples regarding any other marker protein other than GFP fused to the N-

terminal of Bax comprising the amino acid sequence of SEQ ID NO: 2 to be used in detection of the apoptotic event. While the specification in Example 3 shows SEQ ID NO: 1 encoding a probe, the specification has not provided guidance, prediction, and/or working examples regarding the use of this probe in detecting any molecular event.

Thus, one skilled in the art must perform an undue amount of trial and error experimentation which includes searching and screening for any marker protein to present in any cell, modification of any marker protein to be detectable in the cell, and searching and screening for any specific molecular event in any cell which can be detected by the presence of any marker protein wherein the cell is subjected to a permeabilization of the plasma membrane before the detection of the marker protein. General teaching regarding screening and searching for the claimed invention such as using enzyme activity assays is not guidance for making the claimed invention. Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a one skilled in the art to make and/or use the invention commensurate in scope with these claims.

Conclusion

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571)272-0956. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/
Primary Examiner
Art Unit 1652